

114TH CONGRESS  
1ST SESSION

# S. 598

To improve the understanding of, and promote access to treatment for, chronic kidney disease, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 2015

Mr. CARDIN (for himself, Mr. CRAPO, and Mr. NELSON) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To improve the understanding of, and promote access to treatment for, chronic kidney disease, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-  
2 tives of the United States of America in Congress assembled,*

**3 SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Chronic Kidney Dis-  
5 ease Improvement in Research and Treatment Act of  
6 2015”.

**7 SEC. 2. TABLE OF CONTENTS.**

8       The table of contents of this Act is as follows:

See. 1. Short title.

See. 2. Table of contents.

TITLE I—IMPROVING UNDERSTANDING OF CHRONIC KIDNEY  
DISEASE THROUGH EXPANDED RESEARCH AND COORDINATION

- Sec. 101. Identifying gaps in chronic kidney disease research.
- Sec. 102. Coordinating research on chronic kidney disease.
- Sec. 103. Understanding the progression of kidney disease and treatment of kidney failure in minority populations.
- Sec. 104. Identifying Medicare payment disincentives for transplant and post-transplant care.

## TITLE II—PROMOTING ACCESS TO CHRONIC KIDNEY DISEASE TREATMENTS

- Sec. 201. Increasing access to Medicare kidney disease education benefit.
- Sec. 202. Improving access to chronic kidney disease treatment in underserved rural and urban areas.
- Sec. 203. Promoting access to home dialysis treatments.
- Sec. 204. Expanding access for patients with acute kidney injury.

## TITLE III—CREATING ECONOMIC STABILITY FOR PROVIDERS CARING FOR INDIVIDUALS WITH CHRONIC KIDNEY DISEASE

- Sec. 301. Stabilizing Medicare payments for services provided to beneficiaries with stage V chronic kidney disease receiving dialysis services.
- Sec. 302. Providing individuals with kidney failure access to managed care and coordinated care programs.

# 1   **TITLE I—IMPROVING UNDER-** 2   **STANDING OF CHRONIC KID-** 3   **NEY DISEASE THROUGH EX-** 4   **PANDED RESEARCH AND CO-** 5   **ORDINATION**

## 6   **SEC. 101. IDENTIFYING GAPS IN CHRONIC KIDNEY DISEASE** 7           **RESEARCH.**

- 8         (a) REPORT.—Not later than one year after the date  
9         of enactment of this Act, the Comptroller General of the  
10       United States shall develop and submit to Congress a com-  
11       prehensive report assessing the adequacy of Federal ex-  
12       penditures in chronic kidney disease research relative to  
13       Federal expenditures for chronic kidney disease care.

- 14         (b) CONTENTS.—The report required by this section  
15       shall—

1                             (1) analyze the current chronic kidney disease  
2                             research projects being funded by Federal agencies;  
3                             (2) identify, including by surveying the kidney  
4                             care community, areas of chronic kidney disease  
5                             knowledge gaps that are not part of current Federal  
6                             research efforts;  
7                             (3) report on the level of Federal expenditures  
8                             on kidney research as compared to the amount of  
9                             Federal expenditures on treating individuals with  
10                            chronic kidney disease; and  
11                             (4) identify areas of kidney failure knowledge  
12                             gaps in research to assess treatment patterns associ-  
13                             ated with providing care to minority populations  
14                             that are disproportionately affected by kidney fail-  
15                             ure.

16 **SEC. 102. COORDINATING RESEARCH ON CHRONIC KIDNEY  
17                             DISEASE.**

18                             (a) INTERAGENCY COMMITTEE.—The Secretary of  
19                             Health and Human Services shall establish and maintain  
20                             an interagency committee for the purpose of improving the  
21                             coordination of chronic kidney disease research.

22                             (b) REPORTS.—For the purpose described in sub-  
23                             section (a), the interagency committee established under  
24                             such subsection shall issue public reports that—

1                         (1) include a strategic plan, including rec-  
2                         ommendations for—

3                                 (A) improving communication and coordi-  
4                         nation among Federal agencies;

5                                 (B) procedures for monitoring Federal  
6                         chronic kidney disease research activities; and

7                                 (C) ways to maximize the efficiency of the  
8                         Federal chronic kidney disease research invest-  
9                         ment and minimize the potential for unneces-  
10                         sary duplication;

11                         (2) include a portfolio analysis that provides in-  
12                         formation on chronic kidney disease research  
13                         projects, organized by the strategic plan objectives;  
14                         and

15                         (3) address such other topics as the interagency  
16                         committee determines appropriate.

17                         (c) MEETINGS.—The interagency committee estab-  
18                         lished under subsection (a) shall meet not less frequently  
19                         than semi-annually.

20                         **SEC. 103. UNDERSTANDING THE PROGRESSION OF KIDNEY**  
21                         **DISEASE AND TREATMENT OF KIDNEY FAIL-**  
22                         **URE IN MINORITY POPULATIONS.**

23                         Not later than one year after the date of enactment  
24                         of this Act, the Secretary of Health and Human Services  
25                         shall—

- 1                         (1) complete a study on—  
2                             (A) the social, behavioral, and biological  
3                             factors leading to kidney disease;  
4                             (B) efforts to slow the progression of kid-  
5                             ney disease in minority populations that are  
6                             disproportionately affected by such disease; and  
7                             (C) treatment patterns associated with  
8                             providing care, under the Medicare program  
9                             under title XVIII of the Social Security Act, the  
10                            Medicaid program under title XIX of such Act,  
11                            and through private health insurance, to minor-  
12                             ity populations that are disproportionately af-  
13                             fected by kidney failure; and  
14                             (2) submit to Congress a report on the results  
15                             of such study.

16 **SEC. 104. IDENTIFYING MEDICARE PAYMENT DISINCEN-**  
17 **TIVES FOR TRANSPLANT AND POST-TRANS-**  
18 **PLANT CARE.**

19                         Not later than 2 years after the date of enactment  
20                         of this Act, the Secretary of Health and Human Services  
21                         shall submit to Congress a report on any disincentives in  
22                         the payment systems under the Medicare program under  
23                         title XVIII of the Social Security Act that create barriers  
24                         to kidney transplants and post-transplant care for bene-  
25                         ficiaries with end-stage renal disease.

1   **TITLE II—PROMOTING ACCESS**  
2   **TO CHRONIC KIDNEY DIS-**  
3   **EASE TREATMENTS**

4   **SEC. 201. INCREASING ACCESS TO MEDICARE KIDNEY DIS-**  
5                   **EASE EDUCATION BENEFIT.**

6       (a) IN GENERAL.—Section 1861(ggg) of the Social  
7   Security Act (42 U.S.C. 1395x(ggg)) is amended—

8               (1) in paragraph (1)—

9                       (A) in subparagraph (A), by inserting “ or  
10                       stage V” after “stage IV”; and

11                       (B) in subparagraph (B), by inserting “or  
12                       of a physician assistant, nurse practitioner, or  
13                       clinical nurse specialist (as defined in section  
14                       1861(aa)(5)) assisting in the treatment of the  
15                       individual’s kidney condition” after “kidney  
16                       condition”; and

17               (2) in paragraph (2)—

18                       (A) by striking subparagraph (B); and

19                       (B) in subparagraph (A)—

20                               (i) by striking “(A)” after “(2)”;

21                               (ii) by striking “and” at the end of  
22                               clause (i);

23                               (iii) by striking the period at the end  
24                               of clause (ii) and inserting “; and”;

1                                     (iv) by redesignating clauses (i) and  
2                                     (ii) as subparagraphs (A) and (B), respec-  
3                                     tively; and

4                                     (v) by adding at the end the following:  
5                                     “(C) a renal dialysis facility subject to the  
6                                     requirements of section 1881(b)(1) with per-  
7                                     sonnel who—

8                                     “(i) provide the services described in  
9                                     paragraph (1); and

10                                    “(ii) is a physician (as defined in sub-  
11                                     section (r)(1)) or a physician assistant,  
12                                     nurse practitioner, or clinical nurse spe-  
13                                     cialist (as defined in subsection (aa)(5)).”.

14         (b) PAYMENT TO RENAL DIALYSIS FACILITIES.—  
15     Section 1881(b) of such Act (42 U.S.C. 1395rr(b)) is  
16     amended by adding at the end the following new para-  
17     graph:

18                                   “(15) For purposes of paragraph (14), the sin-  
19                                     gle payment for renal dialysis services under such  
20                                     paragraph shall not take into account the amount of  
21                                     payment for kidney disease education services (as  
22                                     defined in section 1861(ggg)). Instead, payment for  
23                                     such services shall be made to the renal dialysis fa-  
24                                     cility on an assignment-related basis under section  
25                                     1848.”.

1       (c) EFFECTIVE DATE.—The amendments made by  
2 this section apply to kidney disease education services fur-  
3 nished on or after January 1, 2016.

**4 SEC. 202. IMPROVING ACCESS TO CHRONIC KIDNEY DIS-  
5 EASE TREATMENT IN UNDERSERVED RURAL  
6 AND URBAN AREAS.**

7       (a) DEFINITION OF PRIMARY CARE SERVICES.—Sec-  
8 tion 331(a)(3)(D) of the Public Health Service Act (42  
9 U.S.C. 254d(a)(3)(D)) is amended by inserting “and in-  
10 cludes renal dialysis services” before the period at the end.

(b) NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP PROGRAM.—Section 338A(a)(2) of the Public Health Service Act (42 U.S.C. 254l(a)(2)) is amended by inserting “, including nephrologists and non-physician practitioners providing renal dialysis services” before the period at the end.

17 (c) NATIONAL HEALTH SERVICE CORPS LOAN RE-  
18 PAYMENT PROGRAM.—Section 338B(a)(2) of the Public  
19 Health Service Act (42 U.S.C. 254l-1(a)(2)) is amended  
20 by inserting “, including nephrologists and non-physician  
21 practitioners providing renal dialysis services” before the  
22 period at the end.

1   **SEC. 203. PROMOTING ACCESS TO HOME DIALYSIS TREAT-**  
2                         **MENTS.**

3                     Section 1834(m)(4)(C)(ii) of the Social Security Act  
4   (42 U.S.C. 1395m(m)(4)(C)(ii)) is amended by adding at  
5   the end the following new subclause:

6                             “(IX) A renal dialysis facility (as  
7                                     defined in section 1881).”.

8   **SEC. 204. EXPANDING ACCESS FOR PATIENTS WITH ACUTE**  
9                         **KIDNEY INJURY.**

10          Section 1881(b) of the Social Security Act (42 U.S.C.  
11   1395rr(b)) is amended—

12                     (1) in paragraph (1), by inserting “or acute  
13                             kidney injury” after “individuals who have been de-  
14                             termined to have end stage renal disease”;

15                     (2) in paragraph (2)(A), by inserting “or acute  
16                             kidney injury” after “end stage renal disease”;

17                     (3) in paragraph (2)(B), by inserting “or acute  
18                             kidney injury” after “end stage renal disease”;

19                     (4) in paragraph (3), in the matter preceding  
20                              subparagraph (A), by inserting “or acute kidney in-  
21                             jury” after “end stage renal disease”;

22                     (5) in paragraph (11)(A), by inserting “or  
23                             acute kidney injury” after “end stage renal disease”;

24                     (6) in paragraph (11)(B), by inserting “or  
25                             acute kidney injury” after “end stage renal disease”;

26                     (7) in paragraph (14)(B)—

- 1                             (A) in clause (ii), by inserting “or acute  
2                             kidney injury” after “end stage renal disease”;  
3                             (B) in clause (iii), by inserting “or acute  
4                             kidney injury” after “end stage renal disease”;  
5                             and  
6                             (C) in clause (iv), by inserting “or acute  
7                             kidney injury” after “end stage renal disease”;  
8                             and  
9                             (8) in paragraph (14)(H)(i), by inserting “or  
10                             acute kidney injury” after “end stage renal disease”.

11 **TITLE III—CREATING ECONOMIC  
12         STABILITY FOR PROVIDERS  
13         CARING FOR INDIVIDUALS  
14         WITH CHRONIC KIDNEY DIS-  
15         EASE**

16 **SEC. 301. STABILIZING MEDICARE PAYMENTS FOR SERV-  
17         ICES PROVIDED TO BENEFICIARIES WITH  
18         STAGE V CHRONIC KIDNEY DISEASE RECEIV-  
19         ING DIALYSIS SERVICES.**

20                     Section 1881(b)(14) of the Social Security Act (42  
21 U.S.C. 1395rr(b)(14)) is amended—

- 22                     (1) in subparagraph (D), in the matter pre-  
23                     ceding clause (i), by striking “Such system” and in-  
24                     serting “Subject to subparagraph (J), such system”;  
25                     and

1                             (2) by adding at the end the following new sub-  
2                             paragraph:

3                         “(J)(i) For payment for renal dialysis services fur-  
4                         nished on or after January 1, 2016, under the system  
5                         under this paragraph—

6                         “(I) the payment adjustment described in  
7                         clause (i) of subparagraph (D) shall not take into  
8                         account comorbidities;

9                         “(II) the payment adjustment described in  
10                        clause (ii) of such subparagraph shall not be in-  
11                        cluded;

12                         “(III) the standardization factor described in  
13                         the final rule published in the Federal Register on  
14                         November 8, 2012 (77 Fed. Reg. 67470), shall be  
15                         established using the most currently available data  
16                         (and not historical data) and adjusted on an annual  
17                         basis, based on such available data, to account for  
18                         any change in utilization of drugs and any modifica-  
19                         tion in adjustors applied under this paragraph; and

20                         “(IV) the Secretary shall take into account rea-  
21                         sonable costs consistent with paragraph (2)(B) when  
22                         calculating such payments.

23                         “(ii) Not later than January 1, 2016, the Secretary  
24                         shall amend the ESRD facility cost report to—

“(I) include the per treatment network fee (as described in paragraph (7)) as an allowable cost; and

4                   “(II) eliminate the limitation for reporting med-  
5       ical director fees on such reports in order to take  
6       into account the wages of a board-certified  
7       nephrologist.”.

**8 SEC. 302. PROVIDING INDIVIDUALS WITH KIDNEY FAILURE  
9 ACCESS TO MANAGED CARE AND COORDI-  
10 NATED CARE PROGRAMS.**

11 (a) EXPANDING ACCESS TO MEDICARE ADVAN-  
12 TAGE.—

13                   (1) ELIGIBILITY UNDER MEDICARE ADVAN-  
14                   TAGE —

(B) CONFORMING AMENDMENT.—Section 1852(b)(1) of the Social Security Act (42 U.S.C. 1395w-22(b)(1)) is amended—

1   (i) by striking subparagraph (B); and  
2   (ii) by striking “BENEFICIARIES.—”  
3   and all that follows through “A  
4   Medicare+Choice organization” and in-  
5   serting “BENEFICIARIES.—A Medicare Ad-  
6   vantage organization”.

7                                     (C) EFFECTIVE DATE.—The amendments  
8   made by this paragraph shall apply with respect  
9   to plan years beginning on or after January 1,  
10   2016.

11                                     (2) EDUCATION.—Section 1851(d)(2)(A)(iii) of  
12                                     the Social Security Act (42 U.S.C. 1395w–  
13                                     21(d)(2)(A)(iii)) is amended by inserting before the  
14                                     period at the end the following “, including any ad-  
15                                     ditional information that individuals determined to  
16                                     have end stage renal disease may need to make in-  
17                                     formed decisions with respect to such an election”.

18                                     (3) QUALITY METRICS.—Section 1852(e)(3)(A)  
19                                     of the Social Security Act (42 U.S.C. 1395w–  
20                                     22(e)(3)(A)) is amended by adding at the end the  
21                                     following new clause:

22                                     “(v) REQUIREMENTS WITH RESPECT  
23   TO INDIVIDUALS WITH ESRD.—In addition  
24                                     to the data required to be collected, ana-  
25                                     lyzed, and reported under clause (i) and

1                    notwithstanding the limitations under sub-  
2                    paragraph (B), as part of the quality im-  
3                    provement program under paragraph (1),  
4                    each MA organization shall provide for the  
5                    collection, analysis, and reporting of data,  
6                    determined in consultation with the kidney  
7                    care community, that permits the measure-  
8                    ment of health outcomes and other indices  
9                    of quality with respect to individuals deter-  
10                  mined to have end stage renal disease.”.

11                 (b) PERMANENT EXTENSION OF MEDICARE ADVAN-  
12                 TAGE ESRD SPECIAL NEEDS PLANS AUTHORITY.—Sec-  
13                 tion 1859(f)(1) of the Social Security Act (42 U.S.C.  
14                 1395w–28(f)(1)) is amended by inserting “, in the case  
15                 of a specialized MA plan for special needs individuals who  
16                 have not been determined to have end stage renal dis-  
17                 ease,” before “for periods before January 1, 2017”.

18                 (c) VOLUNTARY ESRD COORDINATED CARE  
19                 GAINSHARING PROGRAM.—

20                 (1) IN GENERAL.—Section 1881(b) of the So-  
21                 cial Security Act (42 U.S.C. 1395rr(b)) is amended  
22                 by adding at the end the following new paragraph:  
23                 “(15)(A) Not later than January 1, 2017, the Sec-  
24                 retary shall, in accordance with this paragraph, establish  
25                 an ESRD Care Coordination gainsharing program for

1 nephrologists, renal dialysis facilities, and providers of  
2 services that develop coordinated care organizations to  
3 provide a full range of clinical and supportive services (as  
4 described in subparagraph (D)) to individuals determined  
5 to have end stage renal disease.

6        "(B) Under such program, subject to subparagraph  
7 (C), the payment amounts renal dialysis facilities and pro-  
8 viders of services described in subparagraph (A) would  
9 otherwise receive under paragraph (14) and nephrologists  
10 described in subparagraph (A) would otherwise receive  
11 under section 1848 with respect to dialysis services fur-  
12 nished by such a facility, provider, or nephrologist during  
13 a year, shall be increased by a portion of the amount (as  
14 determined by the Secretary) of actual reductions in ex-  
15 penditures under this title attributable to the coordinated  
16 care organization developed by such facility, provider, or  
17 nephrologist involved, taking into account non-dialysis ex-  
18 penditures under parts A and B, during the preceding cal-  
19 endar year. The payment amount under this subparagraph  
20 shall be provided to a nephrologist, renal dialysis facility,  
21 and provider of services that developed the coordinated  
22 care organization not later than March 31 of the year  
23 after the year during which such services are provided by  
24 such nephrologist, facility, or provider.

1       “(C) The aggregate incentive payment amounts pro-  
2 vided under such program for a year may not exceed the  
3 amount equal to 2 percent less than the estimated total  
4 amount of non-dialysis expenditures under parts A and  
5 B for 2017 for items and services that are not related  
6 to dialysis or transplant services.

7       “(D) For purposes of subparagraph (A), the full  
8 range of clinical and supportive services includes at least  
9 the following:

10           “(i) Primary care and other preventative serv-  
11 ices.

12           “(ii) Specialty care for co-morbidities or non-  
13 renal acute conditions, including at least podiatry,  
14 cardiology, and orthopedics.

15           “(iii) Vascular access.

16           “(iv) Laboratory testing and diagnostic imag-  
17 ing.

18           “(v) Pharmacy care management.

19           “(vi) Patient, family, and caregiver education.

20           “(vii) Psychiatric, behavioral therapy, and coun-  
21 seling services.

22       “(E) In providing payment incentive amounts under  
23 such program, the Secretary shall apply a risk adjustment  
24 methodology that—

1           “(i) uses risk adjuster factors applied under  
2       part C; and

3           “(ii) adjusts such payments to exclude the top  
4       2 percent of outliers.

5           “(F) In establishing such program, the Secretary  
6       shall ensure that each of the following is satisfied:

7           “(i) The program allows for all types and sizes  
8       of renal dialysis facilities and providers of services  
9       described in subparagraph (A), including profit and  
10      not-for-profit, urban and rural, as well as all other  
11      types and sizes of such facilities and providers, to  
12      participate.

13          “(ii) The program rewards high quality, effi-  
14       cient facilities and providers through gain-sharing.

15          “(iii) For purposes of determining the actual  
16       reductions in expenditures under this title attrib-  
17       utable to a coordinated care organization described  
18       in subparagraph (A), the program includes a mar-  
19       ket-based benchmark system that will not be rebased  
20       against which such expenditures shall be compared.

21          “(iv) The program results in reductions of ex-  
22       penditures under parts A and B for services that are  
23       not dialysis-related services.

1               “(v) The program allows new applicants to par-  
2               ticipate in the program after the initial implemen-  
3               tation period.

4               “(vi) The program establishes clear quality  
5               metrics in consultation with the kidney care commu-  
6               nity.

7               “(vii) The program provides for waivers of Fed-  
8               eral laws or requirements, in consultation with inter-  
9               ested stakeholders.

10               “(viii) Under such program the Secretary at-  
11               tributes individuals described in subparagraph (A)  
12               who receive treatment through a care coordination  
13               organization described in such subparagraph to such  
14               organization rather than to any other payment  
15               model that requires beneficiary attribution.

16               “(ix) Under such program the Secretary pro-  
17               vides quarterly Medicare parts A and B claims data  
18               to facilities and providers described in subparagraph  
19               (A) participating in such program.

20               “(G) Not later than 3 years after the date of the im-  
21               plementation of the ESRD Care Coordination gainsharing  
22               program, the Secretary shall submit to Congress a report  
23               on the waivers granted under subparagraph (F)(vii) and  
24               the effectiveness of such waivers in allowing the coordina-  
25               tion of care.”.

## 1                   (2) CONFORMING AMENDMENTS.—

2                   (A) SECTION 1881.—Section 1881(b) of the  
3                   Social Security Act (42 U.S.C. 1395rr(b)) is  
4                   amended—5                         (i) in each of paragraphs (12)(A) and  
6                         (13)(A), by striking “paragraph (14)” and  
7                         inserting “paragraphs (14) and (15)”; and  
8                         (ii) in paragraph (14)(A)(i), by insert-  
9                         ing “and paragraph (15)” after “Subject  
10                         to subparagraph (E)”.11                   (B) SECTION 1848.—Section 1848 of the  
12                   Social Security Act (42 U.S.C. 1395w–4) is  
13                   amended by adding at the end the following  
14                   new subsection:15                   “(q) VOLUNTARY ESRD COORDINATED CARE PRO-  
16                   GRAM.—For provisions related to incentive payment  
17                   amounts to nephrologists under the ESRD Care Coordina-  
18                   tion gainsharing program, see section 1881(b)(15).”.19                   (d) PATIENT INFORMATION REQUIREMENT.—The  
20                   Secretary of Health and Human Services shall require  
21                   hospitals that furnish items and services to individuals en-  
22                   titled to benefits under part A of title XVIII of the Social  
23                   Security Act or eligible for benefits under part B of such  
24                   title and who subsequently receive dialysis services at a  
25                   renal dialysis facility (as defined in section 1881 of such

1 Act (42 U.S.C. 1395rr)) to provide to such facility health  
2 information with respect to such individual, including a  
3 discharge summary and co-morbidity information, upon  
4 request of the facility, not later than 7 days after notifica-  
5 tion by the hospital of the provision of such services to  
6 such individual or of the determination that such indi-  
7 vidual has end stage renal disease, as applicable.

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